

**REMARKS**

Applicant's undersigned attorney thanks the Examiner for his comments. Applicant respectfully requests reconsideration of this patent application, particularly in view of the above Amendment and the following remarks.

Applicant's invention is a composition including a microbiological culture media broth for producing a stabilized dihydrolipoic acid (DHLA) compound derived from a once-living source, i.e., at least one live DHLA-producing probiotic organism. Such stabilized DHLA is suitable for use in a medicament and/or nutritional supplement. The microbiological culture media broth includes at least one live stabilized DHLA-producing probiotic organism, R-lipoic acid and at least one nutritive agent.

**Amendment to the Claims**

Claims 4-23 are pending with Claim 13-19 withdrawn. Claims 4-12 and 20-23 have been examined with no claims allowed.

Claims 4 and 21 have been amended to recite a composition comprising a microbiological culture media broth. Support is found in Claims 13 and 16.

Claims 4 and 21 have been further amended to recite that the microbiological culture media broth includes at least one live stabilized dihydrolipoic acid-producing probiotic organism. Support is found throughout the specification.

Claims 5-10, 12, 13, 16, 18, 20 and 22 have been amended in a manner consistent with the amendments made to Claim 4 and 21.

Claim 23 has been canceled.

New Claim 24 is an independent claim directed to an incubated microbiological culture broth comprising at least one live dihydrolipoic-acid producing probiotic organism, R-lipoic acid, tumeric rhizome, and a stabilized dihydrolidpoic acid. The stabilized dihydrolipoic acid is produced by conversion of R-lipoic acid by the at least one probiotic organism during incubation. Support is found throughout the specification and particularly on page 1, lines 24-26, page 2, line 4-8, page 6, lines 20-25 and Claims 13 and 16.

No new matter has been added by this Amendment. Applicant believes that no fees are owed because the number of claims currently pending does not exceed the number originally paid for.

### **Response to Applicant's Arguments – 35 USC §112**

Applicant presumes that arguments presented in the Amendment filed on 15 March 2007 were persuasive and that the rejection of Claims 12 and 20 as being indefinite has been duly withdrawn in view of the lack of further objection to these claims in the present Office Action.

### **Claim Rejections – 35 USC §103**

The rejection of Claims 4-10 and 20-22 under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent 6,368,617 to Hastings et al. in view of Hermann et al (European Journal of Pharmaceutical Sciences, 1996) is respectfully traversed.

The core of Applicant's invention is a composition in the form of a microbiological culture media broth for producing a stabilized DHLA compound that has been derived from a once-living source. Such stabilized DHLA, when consumed as part of a medicament and/or a nutritional supplement, is believed to be capable of sustaining cellular DNA within the body. The stabilized DHLA is produced by feeding a live stabilized dihydrolipoic acid-producing probiotic organism R-lipoic acid and at least one nutritive agent such as, for example, tumeric rhizome. The live probiotic organisms in the microbiological culture media produce a stabilized DHLA compound via a metabolic conversion process as the broth is incubated.

In contrast, Hastings discloses a dietary supplement for promoting, upon ingestion, healthy hormone balance in adult human subjects. The dietary supplement include, in addition to a secretagogue known as Symbiotropin in combination with 7-ketodehydroepiandrosterone (7-keto DHEA), alpha-lipoic acid and/or a probiotic blend of *Bifidobacterium bifidum* and *Lactobacillus acidophilus*.

Hermann discloses that R(+)-enantiomer of alpha-lipoic acid has a greater absolute bioavailability than the S(-)-enantiomer of alpha-lipoic acid when consumed by a human.

The Office Action states that it is obvious to use the enantiomerically pure (R) of lipoic acid from the teachings of Hermann to improve the composition of Hastings. It is thus alleged, in view of MPEP §2144.06 that it is prima facie obvious to combine two compositions, the dietary supplement of Hastings and the R-lipoic acid for human consumption of Hermann, to form a third composition to be used for the very same purpose. Logically, the third composition which results from the combination of the teachings of Hastings and Hermann is a dietary supplement for human consumption.

The Office Action further states that Claims 4-10 are drawn to a composition comprising three parts at least one live probiotic organism, R-lipoic acid and at least one nutritive agent.

Applicant's respectfully submits that the Office Action mischaracterizes Applicant's invention which, as recited in Claims 4 and 21, is a composition comprising a microbiological culture media broth. Said broth contains at least one live stabilized dihydrolipoic acid-producing probiotic organism, R-lipoic acid and at least one nutritive agent such as, for example, curcuma longa.

In the present instance, Applicant is not combining two compositions each taught as dietary supplements for human consumption, in order to form a third dietary supplement for human consumption. In contrast, Applicant has developed a microbiological culture medium, not a dietary supplement for human consumption. Such a microbiological culture media or broth is a substance in which the probiotic organism(s) can grow and produce a stabilized DHLA composition via consumption of the nutritive agent and conversion of the R-lipoic acid. In practice this medium or broth is incubated and reliably produces a naturally-derived, stabilized DHLA compound outside of the human body.

Additionally, Hastings in view Hermann does not disclose or suggest that the resulting dietary supplement, a material intended for human consumption, is or can be used as a microbiological culture media broth to convert R-lipoic acid into stabilized dihydrolipoic acid outside of the human body. In contrast, Hastings discloses that alpha-lipoic acid is included in the dietary supplement as an anti-oxidant which coacts with and regenerates several other anti-oxidants to their active states (col. 3, lines 50-55) while probiotic organisms may be included in

the dietary supplement to promote intestinal health by increasing and maintaining intestinal flora (col. 5, lines 1-3).

For at least the reasons above, Applicant respectfully submits that Hastings in view of Hermann does not disclose or suggest a composition comprising a microbiological culture media broth as recited in amended Claims 4 and 21. Because Claims 5-10 and 20 depend from Claim 4 and Claim 22 depends from Claim 21, these claims are also patentable over Hastings in view of Hermann. Accordingly, reconsideration and withdrawal of this rejection is respectfully requested.

Additionally, in view of statements made in the Office Action regarding the lack of structural relationship between the composition and the phrase “for producing a stabilized dihydrolipoic acid compound, and the mischaracterization of the subject matter of Claims 4 and 21, Applicant has amended these claims to recited that the at least one live probiotic organism is a live stabilized dihydrolipoic acid-producing probiotic organism.

Applicant has also added new Claim 24, which recites a broth containing at least one live dihydrolipoic acid-producing probiotic organism, R-lipoic acid, tumeric rhizome and a stabilized dihydrolipoic acid compound produced by the conversion of R-lipoic acid by the at least one probiotic organism. Applicant believes that new Claim 24 falls within the group elected in Response to the Restriction Requirement filed on 30 August 2006. Applicant therefore respectfully requests examination of new Claim 24 as part of the elected group and further submits that at least for the reasons above, new Claim 24 is also patentable over Hastings in view of Hermann.

The rejection of Claims 11, 12 and 23 under 35 U.S.C. § 103(a) as unpatentable over Hastings in view of Hermann and further in view of U.S. Patent 6,080,401 to Reddy et al. is respectfully traversed.

As discussed above, Hastings in view of Hermann does not disclose or suggest a composition comprising a microbiological culture media broth.

Reddy discloses drugs containing a combination of beneficial micro-organisms, such as probiotic organisms, with drugs of herbal origin, such as *curcuma longa*, for the treatment of a disease or disorder in humans or animals. Reddy, similar to Hastings in view of

Hermann, does not disclose or suggest that such combinations can be used as a microbiological culture media broth for producing a stabilized DHLA compound outside of the human body.

For at least the reasons above, Claim 4 is patentable over Hastings in view of Hermann and further in view of Reddy. Because Claims 11 and 12 depend from Claim 4 these claims are also patentable over Hastings in view of Hermann and further in view of Reddy. Claim 23 has been canceled. Accordingly, reconsideration and withdrawal of this rejection is respectfully requested.

### **Co-Pending Applications**

Applicant hereby brings to the Examiner's attention, U.S. Patent Application Serial No. 11/028,272 a co-pending continuation-part-application of the present application filed on 03 January 2005. Examination of this co-pending application is also being conducted by this Examiner. Accordingly, Applicant believes that the Examiner has full and ready access to the claims of the cited co-pending application. However, Applicant hereby accedes to the Examiner's request for a copy of the currently co-pending claims which are appended to this Submission.

### **Conclusion**

If the Examiner feels that any issues remain regarding this application, then Applicant's undersigned attorney would like to discuss the case with the Examiner. The undersigned can be reached at (312) 327-3327.

Respectfully submitted,

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**Claims of Co-pending U.S. Patent Application Serial No. 11/028,272**

1. (Original) A process for naturally deriving a beneficial compound comprising:

preparing a microbiological culture comprising at least one live probiotic organism and at least one nutritive agent or at least one nutraceutical agent;  
incubating the microbiological culture to initiate probiotic activity;  
halting the probiotic activity;  
harvesting a waste byproduct of the probiotic activity; and  
separating the beneficial compound from the waste byproduct.

2. (Original) The process of claim 1 wherein the at least one live probiotic organism is selected from the group consisting of *Lactobacillus* species, *Bifidobacterium* species, *Enterococcus* species, *Streptococcus thermophilus*, and combinations thereof.

3. (Original) The process of claim 1 wherein the microbiological culture is incubated at a temperature of from about 35°C to about 40°C.

4. (Original) The process of claim 1 wherein the microbiological culture is incubated for a period of from about 24 hours to about 240 hours.

5. (Original) The process of claim 1 wherein the probiotic activity is halted by adding organic ethanol.

6. (Withdrawn) The process of claim 1 wherein:  
the at least one live probiotic organism is selected from the group consisting of *Lactobacillus* species, *Bifidobacterium* species, *Enterococcus* species, *Streptococcus thermophilus*, and combinations thereof,  
the microbiological culture includes at least one nutritive agent and at least one nutraceutical agent which is a source of a B vitamin; and  
the beneficial compound comprises at least one B vitamin coenzyme.
7. (Withdrawn) The process of claim 6 wherein the nutritive agent comprises at least one species of nutritional yeast.
8. (Withdrawn) The process of claim 6 wherein the nutritive agent comprises *Saccharomyces cerevisiae*.
9. (Withdrawn) The process of claim 6 wherein the at least one naturally derived B vitamin coenzyme is selected from the group consisting of 5-methyltetrahydrofolate, 5-deoxyadenosylcobalamin, pyridoxal-5-phosphate, coenzyme A, inositol hexanicotinamide, riboflavin-5-phosphate, thiamin cocarboxylase, inositol, choline, biotin and combinations thereof.
10. (Withdrawn) The process of claim 6 wherein the microbiological culture is incubated for a period of from about 96 hours to about 240 hours.

11. (Withdrawn) The process of claim 1 wherein:  
the at least one live probiotic organism selected from the group consisting of *Lactobacillus* species, *Bifidobacterium* species, *Enterococcus* species, *Streptococcus thermophilus*, and combinations thereof, and  
the microbiological culture includes at least one nutraceutical agent.
12. (Withdrawn) The process of claim 11 wherein the naturally derived beneficial compound comprises at least one polyphenol compound.
13. (Withdrawn) The process of claim 12 wherein the nutraceutical agent comprises a material selected from the group consisting of green tea in whole, chopped or powdered form, at least one polyphenol concentrate, and combinations thereof.
14. (Withdrawn) The process of claim 12 wherein the at least one polyphenol compound is selected from the group consisting of epigallocatechin-3-gallate, epigallocatechin, epicatechin-3-gallate, epicatechin, catechin-3-galate, catechin and combinations thereof.
15. (Withdrawn) The process of claim 12 wherein the microbiological culture is incubated for a period of from about 96 hours to about 144 hours.
16. (Withdrawn) The process of claim 11 wherein the naturally derived beneficial compound is UVI-quinol.
17. (Withdrawn) The process of claim 16 wherein the nutraceutical agent comprises UVI-quinone.
18. (Withdrawn) The process of claim 16 wherein the microbiological culture further comprises at least one nutritive agent.



19. (Withdrawn) The process of claim 18 wherein the at least one nutritive agent comprises tumeric rhizome.

20. (Withdrawn) The process of claim 16 wherein microbiological culture is incubated for a period of from about 168 hours to about 196 hours.